



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,010	12/31/2003	Zhihao Fang	SHE0059.00	5510
21968 7590 02/23/2007 NEKTAR THERAPEUTICS 150 INDUSTRIAL ROAD SAN CARLOS, CA 94070			EXAMINER FIGUEROA, JOHN J	
			ART UNIT	PAPER NUMBER
			1712	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/23/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/751,010

Applicant(s)

FANG ET AL.

Examiner

John J. Figueroa

Art Unit

1712

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 15-20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-4, 6-9 and 11-14 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The 35 U.S.C. 112 rejections in items 7 and 8 on pages 3 and 4 of the Office Action of August 23, 2006 (hereinafter 'OA') have been withdrawn in view of Applicant's amendment to the claims in the response to OA filed November 22, 2006 (hereinafter 'Response').
2. The 35 U.S.C. 102(b) rejection of claims 1-4 and 11-14 as anticipated by United States Patent Number (USPN) 3,301,831 to Orthner et al. (hereinafter 'Orthner') is maintained for the reasons previously made of record in item 10 on page 4 of OA and for the reasons set forth below.
3. The 35 U.S.C. 103(a) rejection of claims 5-9 as unpatentable over Orthner in view of USPN 6,774,180 B2 to Kozlowski et al. (hereinafter 'Kozlowski') in item 12 on page 6 of OA has been withdrawn.

Election/Restrictions

4. Applicant's election with traverse in Response of Group I, claims 1-9 and 11-14, of the restriction requirement made of record in items 1-5 on pages 2 and 3 of OA is acknowledged. The traversal is on the ground(s) that a combined search "does not impose an undue burden on the Examiner." This is not found persuasive because the claims in Group I are drawn to a *method of making* a polymer composition, whereas the

Art Unit: 1712

Group II claims are drawn to a *compound* of a recited formula and a *composition* comprising thereof. The search for the compound of claim 20 alone would require an exhaustive search for the disclosure of the compound anywhere in, for example, the polymeric, biochemical, organic chemical, pharmaceutical and chemical engineering arts. Accordingly, a serious burden would be imposed on the Examiner to search both groups of claims of the restriction requirement.

Therefore, the requirement is still deemed proper and is thus made FINAL.

Claims 10 and 15-20 remain withdrawn from consideration in the present Office Action.

Claim Rejections - 35 USC § 112

5. **The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action**

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1 and 11, and claims 2-4, 6-9 and 12-14 that depend therefrom, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a thiosulfonate polymer *derivative* having the Formula (I), Formula (II) and Formula III), it does not reasonably provide enablement for any other thiosulfonate polymer *derivative*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Art Unit: 1712

The specification discloses the aforementioned chemical structural formulas for the thiosulfonate polymer derivative on pages 13, 16 and 18 of the specification (see also, Examples 1 and 2) but does not provide enablement for any other *derivative* of a thiosulfonate polymer. Given its broadest interpretation, a derivative product(s) of the reaction of a thiosulfonate polymer can be, for example, water, sulfur dioxide or a "Bunte salt" (as disclosed in Orthner), and need not require the derivative to contain a polymer or thiosulfonate at all.

One of ordinary skill in the art, in the absence of undue experimentation, would be unable to determine which of the numerous potential "derivatives" of a thiosulfonate polymer (aside from those encompassed by the aforementioned formulas disclosed in the specification) can be used in the method recited in independent claims 1 and 11.

8. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites the limitations "POLY", "X" and "Y" in lines 1-3, respectively. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102.

9. Claim 3, as amended, and claims 7-9, are also rejected under 35 U.S.C. 102(b) as being anticipated by Orthner. (As discussed above, the rejection of claims 1, 2, 4 and 11-14 as anticipated by Orthner has been maintained for the same reasons made of record in item 5 of OA)

Art Unit: 1712

The 102 rejection over Orthner set forth previously in item 5 on pages 3 and 4 of OA and all the arguments and grounds of rejection therein apply equally herein and thus are incorporated into the instant rejection.

Claim 3 has been have been amended to limit the thiosulfonate to "a three to about 100 thiosulfonate ester of a water-soluble polymer". Claims 7-9 recites the first composition comprising "at least one active agent" or a "biological active moiety".

With regards to claim 3, Orthner discloses a crosslinked polymer condensation products formed from a thiosulfonate (e.g. a Bunte salt, which is a "thiosulfonate polymer *derivative*"), which in turn is formed from reacting a water-soluble thiosulfate with a compound having at least 3 to about 25 groups reactive with thiosulfate moieties, such as a polyalcohol (e.g., glycerine, polyglycerine or hexane triol) or a polyester having at least 3 free hydroxyl groups. (Col. 1, line 22 to col. 2, line 6) The resulting thiosulfonate used to form, e.g. the Bunte salt, would thus have at least three ester groups.

Regarding claims 7-9, it is unclear as to the distinction of "an active agent", as recited in claim 7, from the "biologically active *moiety*" recited in claims 8 and 9. (See specification, page 7, lines 16-20; and page 10, line 26 to page 11, line 7) The specification further defines "active" as including "those functional groups that react readily with electrophilic or nucleophilic groups on other molecules, in contrast to those groups that require strong catalysts or highly impractical reaction conditions in order to react (i.e., "nonreactive" or "inert" groups)." Thus, the thiosulfonate, hydroxyl or ester moieties/groups in the resultant condensation product (obtained from reactants

Art Unit: 1712

comprising a thiosulfate, aliphatic polyalcohol and/or polyester component) disclosed in Orthner, can be considered as an “active moieties”.

Thus, the claims are anticipated by Orthner.

Allowable Subject Matter

10. Claim 5 is objected to as being dependent upon a rejected base claim (claim 1), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 6 would be allowable if rewritten to depend from claim 5 and to overcome the 35 USC 112, second paragraph, rejections.

11. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest a method for making a crosslinked polymer composition comprising providing a first composition comprising at least one thiosulfonate polymer derivative, wherein said at least one thiosulfonate polymer derivative comprises at least three thiosulfonate functional groups and has the formula recited in claim 5; exposing said first composition to a base under conditions sufficient to initiate crosslinking between the thiosulfonate functional groups; and allowing the crosslinking to proceed to form a resultant crosslinked polymer composition, wherein said resultant crosslinked polymer composition can form a hydrogel.

Response to Arguments

The 35 U.S.C 112, Second Paragraph Rejections (items 7 and 8 of OA)

Art Unit: 1712

12. Applicant arguments in Response regarding the captioned 35 U.S.C. 112 rejections have been considered but are deemed moot due to the withdrawal of these rejections in view of Applicant's amendment to the claims in Response.

The 35 U.S.C. 102(b) Rejection over Orthner (item 10 of OA)

13. Applicant's arguments in Response regarding the 35 U.S.C. 102(b) rejection of claims 1-4 and 11-14 as anticipated by Orthner have been fully considered but are deemed unpersuasive.

Applicant's principal argument in Response traversing the grounds of this rejection is that:

"Each of the pending claims recites a "thiosulfonate polymer derivative." ... As its name makes understood, *a thiosulfonate polymer derivative is a polymer bearing a thiosulfonate group*. Schematically, a polymer bearing a thiosulfonate group can be represented as follows ... *wherein "POLY" represents a residue of a polymer*.

Structurally, it is important to note that *this "thiosulfonate" system contains only two oxygen atoms and includes a polymer*. ... In contrast, the "water-soluble thiosulfates" discussed in Orthner et al. are "first of all alkali metal thiosulfates, especially sodium and potassium thiosulfate as well as ammonium thiosulfate." ... Thus, in contrast to the thiosulfonates encompassed within Applicants' claims, it is evident that Orthner's "alkali metal thiosulfate" systems *contain three oxygen atoms and do not include a polymer*.

[Emphasis added.]

Art Unit: 1712

Applicant's arguments are misguided. As discussed above, the phrase "thiosulfonate polymer *derivative*" as recited in independent claims 1 and 11, in its broadest interpretation, can be construed to be any reaction product derivative of a thiosulfonate polymer, such as thiosulfate, sulfur dioxide, water or the Bunte salt precursors discloses in Orthner. Moreover, there is no recitation of "POLY" in said independent claims, and thus no requirement of "a residue of a polymer", due to the absence of a structural chemical formula for the thiosulfonate polymer derivative (except for dependent claim 5).

Thus, the instant claims remain anticipated by Orthner.

The 35 U.S.C. 103(a) Rejection over the Orthner and Kozlowski (item 12 of OA)

14. Applicant's arguments in Response regarding the 35 U.S.C. 103(a) rejection of claims 5-9 as unpatentable over Orthner and Kozlowski have been fully considered and deemed persuasive. Thus, this rejection has been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John J. Figueroa whose telephone number is (571) 272-8916. The examiner can normally be reached on Mon-Thurs & alt. Fri 8:00-5:30pm.

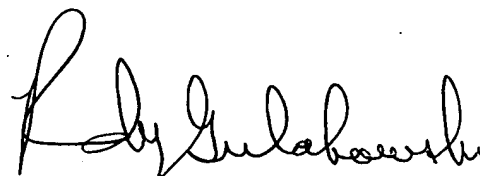
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571) 272-1302. The fax phone

Art Unit: 1712

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JJF/RAG



RANDY GULAKOWSKI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700